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8.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

1. The submitter of this premarket notification is:

Dave Osborn
Quality Program Manager
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810-1085

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This summary was prepared on 15 October, 2001

2. The name of this device is Philips M2/M3/M4 Compact Portable Patient Monitor. Classification names are as follows:

Device Panel	Classification	ProCode	Description
Panel 74 Cardiovascular	None	74 MHX	Physiological Monitor, Patient Monitor
	870.1025, III	74 DSI	Arrhythmia Detector and Alarm
	870.1025, III	74 MLD	Monitor, ST Alarm
	870.2350, II	74 DRW	Electrocardiograph lead switching adapter
	870.1100, II	DSJ	Alarm, Blood-Pressure
	870.1110, II	DSK	Computer, Blood-Pressure
	870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	870.2300, II	74 DRT	Cardiac Monitor
	870.2340, II	74 FYW	Electrocardiograph
	870.1435, II	74 DXG	Computer, Diagnostic, Pre-programmed, Single Function
	870.2900, II	74 DSA	Cable, Transducer and Electrode, including Patient Connector
	870.2850, II	74 DRS	Extravascular Blood Pressure Transducer
Panel 73 Anesthesiology	868.1400, II	73 CCK	Carbon Dioxide Gas Analyzer
Panel 80 General Hospital	880.2910, II	80 FLL	Clinical Electronic Thermometer

3. The new device is substantially equivalent to the previously cleared M3 K971910 and K981576.

4. The modification provides an auscultatory validation reference, according to subclause 4.4.2.1 of AAMI SP-10 for pediatric and adult patients.

5. The new device has the same intended use as the legally marketed predicate devices. M3 is used for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in hospital and medical transport environments.

6. The new device has the same technological characteristics as the legally marketed predicate devices.

7. The results of the validation study indicate that the device performance correlates to auscultatory reference standard according to subclause 4.4.2.1 of AAMI SP-10 for pediatric and adult patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2001

Mr. Dave Osborn
Quality Program Manager
Philips Medical Systems, Inc.
Cardiac and Monitoring Systems
3000 Minuteman Road
Andover, MA 01801

Re: K013427
Trade Name: Philips M3000A/M3046A, (M2/M3/M4) Compact Portable Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor
Regulatory Class: Class III (three)
Product Code: MHX
Dated: November 12, 2001
Received: November 13, 2001

Dear Mr. Osborn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013427

510(k) Number (if known): K013427

Device Name: Philips M3000A/M3046A, (M2/M3/M4) Compact Portable Patient Monitor.

Indications for Use: Intended for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in hospital and medical transport environments.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices

510(k) Number K013427